HOUSE BILL 676

J1 4lr1694

By: **Delegates M. Morgan, Alston, Arikan, Bagnall, Chisholm, Fisher, Howard, Hutchinson, S. Johnson, Kerr, Kipke, Pena–Melnyk, Reilly, ~~and Szeliga~~ Szeliga, Bhandari, Cullison, Guzzone, Hill, Kaiser, R. Lewis, Lopez, Martinez, Rosenberg, Taveras, White Holland, and Woods**

Introduced and read first time: January 25, 2024
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 1, 2024

CHAPTER _____

AN ACT concerning

Right to Try Act – Individualized Investigational Treatments

FOR the purpose of altering certain provisions of law authorizing certain activity by manufacturers of investigational drugs, biological products, or devices under the Right to Try Act to apply to manufacturers of certain individualized investigational treatments; altering the definition of "eligible patient" under the Right to Try Act to include individuals who have life–threatening or severely debilitating illnesses, rather than only individuals who have terminal illnesses; repealing the restriction on the receipt of payments from eligible patients by manufacturers of investigational drugs, biological products, or devices; repealing the prohibition on manufacturers of investigational drugs, biological products, or devices profiting from the provision of the drugs, biological products, or devices; authorizing health insurance carriers, third–party administrators, and government agencies to provide coverage for the cost of investigational treatments and services related to the use of individualized investigational treatments; and generally relating to the Right to Try Act and individualized investigational treatments.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 21–2B–01 through 21–2B–06
Annotated Code of Maryland
(2023 Replacement Volume)

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.
Underlining indicates amendments to bill.
~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

21–2B–01.

(a) In this subtitle the following words have the meanings indicated.

(b) "Carrier" has the meaning stated in § 15–10A–01(c) of the Insurance Article.

(C) "ELIGIBLE FACILITY" MEANS AN INSTITUTION OPERATING UNDER A FEDERALWIDE ASSURANCE FOR THE PROTECTION OF HUMAN SUBJECTS IN ACCORDANCE WITH 42 U.S.C. § 289(A) AND 28 C.F.R. PART 46.

[(c)**] (D)** "Eligible patient" means an individual who:

(1) Has a **[**terminal**] LIFE–THREATENING OR SEVERELY DEBILITATING** illness, attested to by the individual's treating physician;

(2) Has considered all other treatment options currently approved by the United States Food and Drug Administration;

(3) Has received a recommendation from the individual's **[**treating**]** physician for **[**the use of an investigational drug, biological product, or device**] AN INDIVIDUALIZED INVESTIGATIONAL TREATMENT BASED ON ANALYSIS OF THE INDIVIDUAL'S GENOMIC SEQUENCE, HUMAN CHROMOSOMES, DEOXYRIBONUCLEIC ACID, RIBONUCLEIC ACID, GENES, GENE PRODUCTS, INCLUDING ENZYMES AND OTHER TYPES OF PROTEINS, OR METABOLITES**;

(4) (i) Has given informed consent for the use of the **[**investigational drug, biological product, or device**] INDIVIDUALIZED INVESTIGATIONAL TREATMENT**; or

(ii) If the individual is a minor or lacks the mental capacity to provide informed consent, has a parent or legal guardian who has given informed consent on the individual's behalf for the use of the **[**investigational drug, biological product, or device**] INDIVIDUALIZED INVESTIGATIONAL TREATMENT**; **AND**

(5) **[**Is ineligible for or unable to participate in a clinical trial; and

(6)**]** Has documentation from the individual's **[**treating**]** physician that the individual meets the requirements of items (1) through **[**(5)**] (4)** of this subsection.

[(d)**] (E)** "Health occupations board" means a board established under the Health Occupations Article that issues licenses to practice a health occupation in the State.

(F) (1) "INDIVIDUALIZED INVESTIGATIONAL TREATMENT" MEANS A DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT IS UNIQUE TO AND PRODUCED EXCLUSIVELY FOR USE BY AN INDIVIDUAL BASED ON THE GENETIC PROFILE OF THE INDIVIDUAL.

(2) "INDIVIDUALIZED INVESTIGATIONAL TREATMENT" INCLUDES INDIVIDUALIZED GENE THERAPY, ANTISENSE OLIGONUCLEOTIDES, AND INDIVIDUALIZED NEOANTIGEN VACCINES.

[(e)**] (G)** "Informed consent" means a written document prepared using the informed consent form developed by the Office of the Attorney General in accordance with **[**§ 21–2B–02(d)(1)**] § 21–2B–02(B)(1)** of this subtitle that:

(1) Is signed by the patient or a parent or legal guardian of the patient;

(2) Is attested to by the patient's treating physician and a witness; and

(3) At a minimum:

(i) Explains the currently approved products and treatments for the **[**disease or condition**] LIFE–THREATENING OR SEVERELY DEBILITATING ILLNESS** from which the patient suffers**, INCLUDING ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT, IF KNOWN TO THE TREATING PHYSICIAN, THAT MIGHT BE ADVANTAGEOUS TO THE PATIENT**;

(ii) Attests to the fact that the patient concurs with the patient's treating physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

(iii) Identifies clearly the specific proposed **[**investigational drug, biological product, or device**] INDIVIDUALIZED INVESTIGATIONAL TREATMENT** that the patient is seeking to use;

(iv) Informs the provider and eligible patient of any known ~~or~~**,** anticipated**, OR REASONABLY FORESEEABLE** side effects, risks, or reported patient discomfort that is likely related to the treatment;

(v) Describes the best and worst potential outcomes of using the **[**investigational drug, biological product, or device**] INDIVIDUALIZED INVESTIGATIONAL TREATMENT** with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment, based on the treating physician's

knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(vi) Makes clear that the patient's carrier and health care provider are not obligated to pay for any care or treatments that are necessary as a result of the use of the **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT** except as required by federal or State law or contract;

(vii) Makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT** and that hospice care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements; ~~and~~

(viii) States that the patient understands that the patient may be liable for all expenses relating to the use of the **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT** and that this liability extends to the patient's estate, but not the heirs or legatees of the patient**; AND**

(IX) INCLUDES A STATEMENT DESCRIBING THE EXTENT TO WHICH CONFIDENTIALITY OF RECORDS THAT IDENTIFY THE PATIENT WILL BE MAINTAINED.

[(f) "Investigational drug, biological product, or device" means a drug, biological product, or device that:

(1) Has successfully completed Phase I of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration; and

(2) Remains under investigation or in a clinical trial approved by the United States Food and Drug Administration.

(g) "Terminal illness" means a disease or condition that, without life–sustaining procedures, will result in death or a state of permanent unconsciousness from which recovery is unlikely within 12 months.**]**

(H) "LIFE–THREATENING" HAS THE MEANING STATED IN 21 C.F.R. § 312.81.

(I) "SEVERELY DEBILITATING" HAS THE MEANING STATED IN 21 C.F.R. § 312.81.

21–2B–02.

(a) A manufacturer of an **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT OPERATING WITHIN AN ELIGIBLE FACILITY AND IN COMPLIANCE WITH ALL LAWS APPLICABLE TO AN ELIGIBLE FACILITY** may:

(1) Provide the manufacturer's **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT** to an eligible patient without compensation; or

(2) **[**Subject to subsection (b) of this section, require**]** **REQUIRE** an eligible patient to pay the costs of or associated with the manufacture of the **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT** provided to the eligible patient.

[(b) (1) Any payment required by a manufacturer under subsection (a)(2) of this section shall be limited to the recovery of the costs of or associated with the manufacture of the specific investigational drug or biological product dosages or devices provided to the eligible patient.

(2) A manufacturer of an investigational drug, biological product, or device may not profit from providing an investigational drug, biological product, or device provided to an eligible patient.

(c) After the date that an eligible patient begins taking or using the investigational drug, biological product, or device and during the time the eligible patient is taking or using the investigational drug, biological product, or device, the manufacturer shall notify the eligible patient and the eligible patient's health care provider of any side effects or risks associated with the investigational drug, biological product, or device that are required to be disclosed to the United States Food and Drug Administration during the drug approval process.**]**

[(d)**]** **(B)** (1) The Office of the Attorney General shall develop an informed consent form that:

(i) Complies with the requirements of **[**§ 21–2B–01(e)(3)**]** **§ 21–2B–01(G)(3)** of this subtitle;

(ii) Includes instructions for the physician or patient on how to complete the form; and

(iii) Provides spaces for a physician to include the information relating to a particular patient and the physician's recommendation for the patient.

(2) This subsection may not be construed to prohibit a treating physician or a manufacturer of an **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT** from including additional information

or advisements with the informed consent form developed under paragraph (1) of this subsection.

21–2B–03.

(a) A health occupations board may not revoke, fail to renew, suspend, or take any action against a health care provider's license based solely on the health care provider's recommendation to an eligible patient regarding access to or treatment with an **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT**.

(b) The Department may not take action against a health care provider's Medicare certification based solely on the health care provider's recommendation that an eligible patient have access to an **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT** or the health care provider's treatment of an eligible patient with an **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT**.

21–2B–04.

(a) An official, employee, or agent of the State may not block or attempt to block an eligible patient's access to an **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT**.

(b) This section does not prohibit a licensed health care provider from providing counsel, advice, or a recommendation that is consistent with medical standards of care.

21–2B–05.

This subtitle does not create a private cause of action against a manufacturer of an **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT** or against another person involved in the care of an eligible patient using the **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT** for any harm to the eligible patient resulting from the **[**investigational drug, biological product, or device**]** **INDIVIDUALIZED INVESTIGATIONAL TREATMENT** if the manufacturer or other person is complying in good faith with this subtitle and has exercised reasonable care.

21–2B–06.

(A) This subtitle does not affect the coverage requirements under Title 15, Subtitle 8 of the Insurance Article.

(B) A CARRIER, THIRD–PARTY ADMINISTRATOR, OR GOVERNMENT AGENCY MAY PROVIDE COVERAGE FOR THE COST OF AN INDIVIDUALIZED INVESTIGATIONAL

TREATMENT OR THE COST OF SERVICES RELATED TO THE USE OF AN INDIVIDUALIZED INVESTIGATIONAL TREATMENT UNDER THIS SUBTITLE.

(C) THIS SUBTITLE DOES NOT REQUIRE:

(1) A GOVERNMENT AGENCY TO PAY COSTS ASSOCIATED WITH THE USE, CARE, OR TREATMENT OF AN INDIVIDUAL WITH AN INDIVIDUALIZED INVESTIGATIONAL TREATMENT; OR

(2) A HOSPITAL OR ANOTHER HEALTH CARE FACILITY TO PROVIDE NEW OR ADDITIONAL SERVICES UNLESS APPROVED BY THE HOSPITAL OR HEALTH CARE FACILITY.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2024.

Approved:

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Governor.

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Speaker of the House of Delegates.

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President of the Senate.